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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/864,488 | 05/24/2001 | Marcia A. Wise | 7733.D2 | 3552 |

| EXAMINER | |
|-----------------|--|
| GRAY, PHILLIP A | |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3767 | |

| MAIL DATE | DELIVERY MODE |
|------------|---------------|
| 10/09/2007 | PAPER |

7590 10/09/2007
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/864,488

Applicant(s)

WISE ET AL.

Examiner

Phillip Gray

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56 and 59-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56, 59-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to applicant's communication of 7/23/2007.

Response to Arguments

Applicant's arguments filed 7/23/2007 have been fully considered but they are not persuasive. It is examiners position that Wijay does disclose "a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated the first balloon seals the distal end of the first lumen to prevent blood flow thereinto". Examiner has clearly identified the elements of the sealing balloons and distal end of the first lumen (see rejection below) and is of the position that these elements identified are capable of "when inflated the first balloon seals the distal end of the first lumen to prevent blood flow thereinto". Examiner is reading the later portion of the claim limitation as a functional/operational limitation.

It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed (i.e. a functional limitation) does not impose any structural limitations upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. Further, where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In addition, where there is reason to

believe that such functional limitation may be an inherent characteristic of the prior art reference, applicant is required to prove that the subject matter shown in the prior art reference does not possess subject matter shown in the prior art reference does not possess the characteristic relied upon.

In response to applicant's argument that Wijay does not disclose "when inflated the first balloon seals the distal end of the first lumen to prevent blood flow therein", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has not provided credible evidence to overcome the examiners position.

Applicant is reminded that during examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). Under this level of scrutiny, the elements disclosed in Wijay and the prior art of record are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

Claim Rejections - 35 USC § 112(2nd time)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 56, it is unclear how applicant a catheter includes a first and second lumens extending there through from a proximal end of the catheter to a distal end of the catheter thereof when it appears from the drawings that the catheter has one distal end and two separate proximal ends. Examiner is still unclear how a device with two lumens there through (from proximal to distal end) and containing two hubs is a "Y-shaped adapter)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56, 59-66, 68-69, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Wijay et al. (U.S. Patent Number 5,158,540). Wijay discloses a low profile angioplasty perfusion catheter and method of use, which is insertable through a guiding catheter (see abstract, figures 1-4). Wijay discloses and teaches (and is fully capable of being) a system for establishing intermittent fluid communication within a

patient's bloodstream, and comprises a catheter with first (such as annular passage 30) and second lumens (26) (see figures 2, 3, and paragraph at column 2 line 49-68), a first sealing balloon (16) positionable within the first lumen to prevent blood (or fluid) flow therein (or through) and a deflation mechanism for deflating the balloon (not numbered but described and to be connected to connection 3)(see detailed description at column 3 lines 49-61). Further Wijay discloses a method of sealing the catheter that comprises the acts of advancing the first deflated balloon (22) along the first lumen (30) and inflating the balloon to seal the lumen at the distal end thereof which would prevent fluid flow from entering or exiting (see description of use at column 4 lines 10-46) the distal end of the lumen. Wijay discloses that the balloon could be **selectively** inflated or deflated (see column 3 line 54-55) to seal passage 30 which is in fluid communication between blood vessel site and proximal end of catheter (nearer section 2 as in figure 1). Therefore it is examiners position since the proximal balloon can be selectively inflated and deflated (and since it blocks the flow through passage 30 while inflated) when the balloon is deflated ingress or egress of fluid flow through passage 30 would occur. And it is examiners position that this deflation (as previously noted) would take place while the catheter is in the blood vessel site. Further Wijay discloses a stem (near 14) within the lumen, and further the stem is fully capable of being selectively displaceable along the lumen through the central opening of the in the seal (as shown in figure 1 and describe in columns 2-4 generally). There are further ports adjacent the proximal end by which a flushing liquid under pressure is displaced within the lumen (i.e. 2,3,4,28, or 7). Further Wijay discloses steps of advancing a first balloon along a catheter and inflating

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the balloon to seal the catheter, deflating the balloon to open the seal and causing ingress or egress, further the balloon (and Wijay PTCA catheter) is withdrawn from the guiding catheter after the balloon is deflated (see column 2-4), and this method may be done multiple times for multiple treatments (since it is selectable) and it is examiners position that the lumen is purged with saline (column 4). Wijay discloses a device that contains a catheter (8, or 13) a balloon with stem (16) and a deflating mechanism and port (discussed above) and these elements are fully capable of satisfying all structural, operational, functional, and spatial limitations of the claims as currently written.

The following other prior art reads on the claims as currently written, and appropriate rejections are made below. Each are similar perfusion catheters and methods of use and perform similarly to the prior art disclosed above. See rejections below:

Claims 56, 59-66, 68-69, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski et al.(U.S. Patent 4,771,777). As discussed above and see figures 9 and see catheter 14 balloon 82 and stem 77 port 26 for example.

Claims 56, 59-66, 68-69, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Calderon (U.S. Patent 4,867,742). As discussed above and see figures 2,3, and 5 and catheter 52, ballon 56 , and ports 58,54,26, or 14.

Claims 56, 59-66, 68-69, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Cannon (U.S. Patent 5,403,274). As discussed above and see figures 1-3 and catheter 18 balloon 44 with stem near 32 and ports shown in figure 1 at proximal end of catheter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 59-64 are rejected under 35 U.S.C. 102(b) as anticipated by Wijay (as described above) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wijay in view of Burns et al U.S. Pat. No. 5,176,698. Wijay discloses the method substantially as claimed except for explicitly stating purging the first lumen. Burns discloses purging

the first lumen (abstract and entire specification). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to purge the catheter of Wijay as taught by Burns to vent unwanted gases and liquids. As to claims 60-62 (Burns col. 2) as to claim 63, (figure 6); as to claim 64, (the terminating act is performed by purging see above)

Claims 70-72, 74-79 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijay or alternatively Horzewski et al.(U.S. Patent 4,771,777), or alternatively Calderon (U.S. Patent 4,867,742) or alternatively Cannon (U.S. Patent 5,403,274) (see above). Wijay and alternatively Horzewski/Calderon/ or Cannon discloses the claimed invention and method except for being a side by side nonconcentric catheter tube/balloon. (applicant is merely attempting to claim two of the identical aforementioned tubes not having a common center) It would have been obvious to one having ordinary skill in the art at the time the invention was made to duplicate the device of Wijay or Horzewski/Calderon/ or Cannon, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8 (CA7 1977), and this would provide twice the output or input capabilities as well.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


PAG

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

